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**REMARKS**

Applicants thank the Examiner for the very thorough consideration given the present application.

Claims 1-18 are now present in this application. Claims 1, 6, 11 and 18 are independent.

By this amendment, claim 6 is amended, and claim 17 is added. No new matter is involved.

Reconsideration of this application, as amended, is respectfully requested.

**Election of Species Requirement and Withdrawal from Consideration of Claim 17**

The outstanding Office Action has improperly withdrawn consideration of claim 17 on its merits. As explained in the Amendment filed on June 26, 2008, claim 17 is fully supported by Figs. 5-9, which is the species that Applicants elected. Thus, claim 17 is drawn to an elected species.

Because of this, claim 17 has to be examined on its merits and the failure to do so is improper.

The rationale that, because claim 17 depends from claim 1, it is drawn to a non-elected species, is incorrect. What is correct, however, is that because claim 17 reads on the elected species of Figs. 5-9, claim 17 is directed to the elected species and must be examined on its merits.

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Another conclusion to be drawn from the fact that claim 17 depends from claim 1, is that claim 1 is a generic claim, and should be examined on its merits, also.

Accordingly, examination of claim 17 on its merits, and withdrawal of the finality of the outstanding Office Action, and preparation of a new Office Action are respectfully requested.

Moreover, because the finality of the outstanding Office Action is premature and has to be withdrawn, it is proper to enter this Amendment as a matter of right.

Should the Examiner decline to do this, Applicants respectfully request that this request be considered a petition under 37 CFR §1.181 and 1.44 for the Commissioner to exercise supervisory authority and require the Examiner to do so.

#### **Priority Under 35 U.S.C. § 119**

Applicants thank the Examiner for acknowledging Applicants' claim for foreign priority under 35 U.S.C. § 119, and receipt of the certified priority documents.

#### **Entry of Amendments**

Applicants respectfully submit that entry of this Amendment is proper because the finality of the outstanding Office Action is premature, for reasons discussed below, and should be withdrawn. Accordingly, entry of this Amendment is proper as a matter of right.

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**Rejections under 35 U.S.C. §103**

Claims 6 and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Design Patent 368,965 to Nakata et al. ("Nakata") in view of U.S. Patent 6,305,326 to Suchowski et al. ("Suchowski"). This rejection is respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

Because the rejection is based on 35 U.S.C. §103, what is in issue in such a rejection is "the invention as a whole, "not just a few features of the claimed invention. Under 35 U.S.C. §103, " [a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter *as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The determination under §103 is whether the claimed invention *as a whole* would have been obvious to a person of ordinary skill in the art at the time the invention was made. See *In re O'Farrell*, 853 F.2d 894, 902, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988). In determining obviousness, the invention must be considered as a whole and the claims must be considered in their entirety. See *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1567, 220 USPQ 97, 101 (Fed. Cir. 1983).

In rejecting claims under 35 U.S.C. §103, it is incumbent on the Examiner to establish a factual basis to support the legal conclusion of obviousness. See *In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the Examiner is expected to make the factual determinations set forth in *Graham v John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), and to provide a reason why one of ordinary skill in the pertinent art would have

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been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some teaching, suggestion or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. *See Uniroyal Inc. v. F-Wiley Corp.*, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988), *cert. denied*, 488 U.S. 825 (1988); *Ashland Oil, Inc. v Delta Resins & Refractories, Inc.*, 776 F.2d 281, 293, 227 USPQ 657, 664 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986); *ACS Hospital Systems, Inc. v Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). These showings by the Examiner are an essential part of complying with the burden of presenting a *prima facie* case of obviousness. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *See In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783 84 (Fed. Cir. 1992). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be suggested or taught by the prior art. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1970). All words in a claim must be considered in judging the patentability of that claim against the prior art. *See In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

A suggestion, teaching, or motivation to combine the prior art references is an "essential evidentiary component of an obviousness holding." *See C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998). This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are

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not "evidence." *See In re Dembiczak*, 175 F.3d 994 at 1000, 50 USPQ2d 1614 at 1617 (Fed. Cir. 1999).

Moreover, it is well settled that the Office must provide objective evidence of the basis used in a prior art rejection. A factual inquiry whether to modify a reference must be based on objective evidence of record, not merely conclusory statements of the Examiner. *See In re Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).

Furthermore, during patent examination, the PTO bears the initial burden of presenting a *prima facie* case of unpatentability. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785788 (Fed. Cir. 1984). If the PTO fails to meet this burden, then the Applicant is entitled to the patent. Only when a *prima facie* case is made, the burden shifts to the applicant to come forward to rebut such a case.

Claim 6, as amended, recites tooth-hardening apparatus for a teething infant, comprising a plate shaped first tooth-hardening member having a first surface provided with a plurality of first projections, wherein the plate lies in a plane; and a plate shaped second tooth-hardening member having a second surface provided with a plurality of second projections; wherein the plate shaped second tooth-hardening member is arranged at a periphery of the first tooth-hardening member and is extended from the periphery of the plate shaped first tooth hardening member in the plane in which the plate shaped first tooth lies, the first surface of the first tooth-hardening member and the second surface of the second tooth-hardening member are formed of respective materials which have hardnesses different from each other, and wherein the first surface of the first tooth-hardening member is harder than the second surface of the second tooth-hardening member which is arranged at the periphery of the first tooth-hardening member.

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Applicants respectfully submit that Nakata and Suchowski are directed to fundamentally different devices from one another and from the claimed invention, with significant structural differences, and are directed to solving different problems with significantly different structures, so much so, that these two references teach away from being combined, as suggested, in this rejection

Nakata is directed to a teeth correction toy, presumably for a human infant, a conclusion supported by the fact that an Internet search of Pigeon Corporation, the assignee of the Nakata design patent, resulted in its 2004 Annual Report which indicates that it handles, among other items, teething products and other human infant (baby) related items. See the 16 page 2004 Annual Report of Pigeon Corporation, attached hereto.

Nakata does not disclose that its teeth correction toy is a tooth hardening device, as claimed. Nor does Nakata disclose that its teeth correction surfaces have different hardnesses. Even the Office Action admits that Nakata fails to disclose that its toy's teeth correcting member surfaces have different hardnesses.

In an attempt to remedy this deficiency, the Office Action turns to Suchowski, which explicitly states that it is directed to a synthetic chew toy for dogs having a rigid synthetic frame that supports a softer chew portion. However, like Nakata, Suchowski does not explicitly teach that its invention is a tooth hardening device. In other words, neither of the two applied references discloses that their devices are teeth hardening devices, despite the fact that this is a positively recited feature of Applicants' claimed invention.

Furthermore, Suchowski only discloses two different hardness materials in the context of the rigidity of its harder material to act as a frame with bulbous portions to make it resemble a dog bone and to support the softer chew portion of the device. Suchowski fails to provide any incentive to

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use different hardness materials other than in the context of using the harder material because of its rigidity to form a frame with bulbous portions that make the frame appear like a bone for a dog to chew on.

Applicants respectfully submit that one of ordinary skill in the art would not look to Suchowski for using two different softness materials in a context other than using the harder, more rigid, material as a support frame to enclose a uniquely structured soft chew part and to provide a dog bone shape to the support frame.

The Office Action is using Suchowski in a much broader context than its disclosure justifies for the aforementioned reasons, and for the following reasons.

Nakata's toy is not disclosed as having a frame that supports and encloses a soft chew area, so there would be no incentive to look to Suchowski to use a rigid material for Nakata's non-existent frame.

Looking at Nakata, it does appear to have bulbous ends, but there would be no incentive to modify them to make them rigid and have some or all of the rest of the toy structure be soft because (1) Nakata's toy is not designed to appeal to a dog; (2) Nakata has no disclosure of a need to support a soft chewy structure to clean a dog's teeth, as does Suchowski; and (3) the cross-sectional views of Nakata show that the bulbous portions of Nakata appear to be supported by the central portion, not *vice-versa*, as in Suchowski.

Additionally, Nakata's teeth correction device for a human infant is used by an infant with no teeth and is in the process of cutting teeth and is designed to overcome the pain associated with cutting teeth, whereas a chew toy for a dog is designed for a puppy that is born with its teeth in place and is not cutting teeth.

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Also, Suchowski has a fundamentally different structure than that of Nakata, which teach away from the proposed combination of these references. For example, Nakata discloses and claims two plate shaped members that lie in the same plane, whereas Suchowski's softer projections 345 are located above and below the plane in which the rigid frame 200 lies.

Furthermore, the softer portion of Suchowski has a fundamentally different vertical cross-sectional structure than that of its relatively harder frame, whereas Nakata's first tooth-hardening member has a similar vertical cross-section with respect to the vertical cross-section of Nakata's second tooth-hardening member.

The Office Action speculates that it would be obvious to make the first tooth-hardening member of Nakata to be made of a harder material than the second tooth-hardening member, as taught by Suchowski, "for increased chewing pleasure." Applicants respectfully disagree for the numerous reasons set forth above, which teach away from making the proposed combination of these two significantly different references, and because the possibility of a dog achieving greater chewing pleasure from using Suchowski's chew toy has not been shown (by objective factual evidence) to correspond to, or correlate with, a teething baby receiving increased chewing pleasure with its teeth correction toy.

Applicants respectfully submit that the Office Action does not provide objective factual evidence that one of ordinary skill in the art of the claimed invention, which is human infant teething devices, would have a proper incentive to look at Suchowski, with its significant structural and functional differences and overall purpose differences, and to overlook its significant structural and functional differences, and to just arbitrarily change the material of selected portions of the significantly different Nakata toy, to arrive at the claimed invention.

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In response to these arguments, the Office Action concludes that these arguments are immaterial to the combination because softer portions in any chewing device (whether it is for dogs or children) are shown to be known in the art, and that because the specific structures of Suchowski's device have not been relied on in the rejection, the arguments in this regard are not persuasive.

In reply to this response, Applicants respectfully submit that this response begs the question it addresses and totally ignores the thrust of Applicant's arguments in direct contravention of the requirement in MPEP §707.07(f) that the Examiner answer the substance of each argument. This response merely brushes aside the substance of Applicant's arguments instead of answering their substance. This also denies Applicants fundamental substantive and procedural due process as required by the Administrative Procedures Act. See in this regard, *In re Zurko*, 119 S.Ct. 1816, 50 USPQ2d 1930 (1999), and *In re Gartside*, 53 USPQ2d 1769 (Fed. Cir. 2000), as well as MPEP §707.07(a).

Applicants are entitled to have the finality of the outstanding Office Action withdrawn because of this, and are also entitled to receive another Office Action which answers the substance of those arguments on their merits.

Applicants respectfully submit that what is in issue is the invention as a whole, and that it is not proper for an Examiner to disregard the entire disclosure of a reference, such as Suchowski, and lift only certain bits and pieces of a reference out of the context in which that reference discloses them, as explained above with respect to Suchowski, as has been done here.

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Additionally, Applicants respectfully submit that most dogs have much larger mouths than do human babies, so that using a dog's chew toy would not be conducive to, or lead one of ordinary skill in the art, to provide two different plate members at different peripheral positions of the tooth hardening device for a child's tooth hardening development.

In this regard, Applicants note that, due to features of the claimed invention, a five month old infant can easily and securely chew the softer second surface of the second tooth hardening member which is arranged outside the first tooth hardening member, to harden its teeth through training.

When an infant reaches seven months of age, for example, that infant can chew. The harder first surface of the first tooth hardening member which is arranged inside of the second tooth hardening member, to harden its teeth through training (as disclosed, for example, on page 8, lines 12-20 of this Application. A seven month old infant can easily chew the first surface of the first tooth-hardening member, even if the first tooth hardening member is located inside of the tooth hardening member, due to the development of additional teeth.

The Office Action also refers, not in the body of the rejection, but solely in its response on page 4, to U.S. Patent Application Publication 2003/0181948 to Dunn et al. ("Dunn") for disclosing some portions of a teething/chewing device for babies has some portions that are softer than adjacent portions.

Applicants do not understand why this reference is discussed when it is not used to reject the claims, and respectfully submit that it is not proper to use in an Office Action to respond to Applicants' arguments unless it is explicitly relied on in the rejection to which

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**Applicants' arguments are directed. Clarification of why this reference is used in such an unorthodox manner is respectfully requested.**

Nevertheless, Applicants point out that Dunn's tether toy arranges different hardness links alternatively adjacent to one another in a figure eight annular shape, which differs substantially from the shape of the claimed invention.

Accordingly, Applicants respectfully submit that the Office Action does not make out a *prima facie* case of obviousness of the claimed invention based on these applied references.

Reconsideration and withdrawal of this rejection of claims 6 and 10 are respectfully requested.

Claims 7 and 8 stand rejected under 35 USC §103(a) as being unpatentable over Nakata in view of Suchowski and further in view of U.S. Patent 2,532,116 to Monaco. This rejection is respectfully traversed.

Claim 7 positively recites that the first hardening member has a space formed substantially in a center portion of the first tooth-hardening member, the space being contained within two transparent covers which abut one another.

Neither applied reference contains such a positively recited combination of features. So, no matter how these references are combined, they cannot result in, or otherwise render obvious, the claimed invention.

Additionally, because Monaco is not applied to remedy the aforementioned deficiencies in the Nakata-Suchowski reference combination, even if, for sake of argument only, one of ordinary skill in the art were properly motivated to modify the Nakata-Suchowski reference

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combination in view of Monaco, as suggested, the resulting modified version of Nakata would not meet or otherwise render obvious, the claimed invention.

The outstanding Office Action completely fails to respond to these arguments in direct contravention of the requirement in MPEP §707.07(f) that the Examiner answer the substance of each argument. This response merely brushes aside the substance of Applicant's arguments instead of answering their substance. This also denies Applicants fundamental substantive and procedural due process as required by the Administrative Procedures Act. See in this regard, *In re Zurko*, 119 S.Ct. 1816, 50 USPQ2d 1930 (1999), and *In re Gartside*, 53 USPQ2d 1769 (Fed. Cir. 2000), as well as MPEP §707.07(a).

Accordingly, Applicants respectfully submit that the Office Action does not make out a *prima facie* case of obviousness of the claimed invention based on these applied references.

Reconsideration and withdrawal of this rejection of claims 7 and 8 are respectfully requested.

Claim 9 stands rejected under 35 USC §103(a) as being unpatentable over Nakata in view of Suchowski and U.S. Patent 2,532,116 to Monaco, and further in view of U.S. Patent 1,117,093 to Ripley. This rejection is respectfully traversed.

Initially, the Nakata-Suchowski-Monaco reference combination does not disclose or suggest, or otherwise render obvious claim 7, from which claim 9 depends, for reasons discussed above. Moreover, Ripley is not applied in this rejection to remedy the aforementioned deficiencies of the Nakata-Suchowski-Monaco reference combination with respect to claim 7. So even if, solely for sake of argument, that one of ordinary skill in the art were properly motivated to modify the

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Nakata-Suchowski-Monaco reference combination in view of Ripley, as suggested, the resulting modification of Nakata would still not be met, suggested, or otherwise rendered obvious.

Furthermore, Ripley does not disclose the abutment feature of the transparent covers, which is an additional reason why this reference combination does not render obvious the claimed invention.

The outstanding Office Action completely fails to respond to these arguments in direct contravention of the requirement in MPEP §707.07(f) that the Examiner answer the substance of each argument. This response merely brushes aside the substance of Applicant's arguments instead of answering their substance. This also denies Applicants fundamental substantive and procedural due process as required by the Administrative Procedures Act. See in this regard, *In re Zurko*, 119 S.Ct. 1816, 50 USPQ2d 1930 (1999), and *In re Gartside*, 53 USPQ2d 1769 (Fed. Cir. 2000), as well as MPEP §707.07(a).

Accordingly, Applicants respectfully submit that the Office Action does not make out a *prima facie* case of obviousness of the claimed invention based on these applied references.

Reconsideration and withdrawal of this rejection of claim 9 are respectfully requested.

**New Claim 18**

Claim 18 has been added for the Examiner's consideration. Applicants submit that claim 17, which is fully supported by Applicant's disclosure as shown in Figs. 5-9 and in the portions of the specification describing these figures, including from page 6, line 35 through page 10, line 24, defines features that are neither disclosed nor suggested by any of the applied art and are therefore allowable.

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Applicants further note that claim 18 is directed to the elected invention, reading on the elected embodiment of Figs. 5-9.

**Additional Cited Reference**

Because the reference newly cited by the Examiner has not been utilized to reject the claims, but has been cited to rebut Applicants' arguments, Applicants respectfully ask the Examiner to either modify the rejections to include that reference as part of the rejection, or withdraw the portion of the Office Action that relies on this reference. Applicants should not be subjected to this improper citation and reliance on a reference that is not made part of the rejection.

**Conclusion**

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot, and Applicants have clearly pointed out why the finality of the outstanding Office Action should be withdrawn, claim 17 examined on its merits in the next Office Action, and the current Amendment be entered as a matter of right.. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn, and that a new Office Action be prepared and mailed which additionally examines claims 17 and 18 on their merits. It is believed that a full and complete response has been made to the outstanding Office Action. Applicants also respectfully submit that the present application is in condition for allowance.

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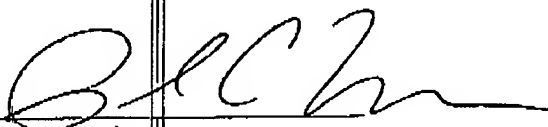
If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone Paul C. Lewis, Registration No. 43,368, at (703) 205-8000, in the Washington, D.C. area.

Prompt and favorable consideration of this Amendment is respectfully requested.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: March 2, 2009

Respectfully submitted,

By   
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